

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

VISTA HEALTHPLAN, INC., et al.

CIVIL ACTION

Plaintiffs,

No. 06-CV-01833

v.

Honorable Mitchell S. Goldberg

CEPHALON, INC., et al.

JURY TRIAL DEMANDED

Defendants.

**AMENDED CONSOLIDATED CLASS ACTION COMPLAINT OF END-PAYORS**

Plaintiff Vista Healthplan, Inc. and the others identified herein (“Plaintiffs”), on behalf of themselves and others similarly situated, allege, upon knowledge as to themselves and their own acts, and upon information and belief as to all other matters, as follows.

**NATURE OF THE ACTION**

1. This is a civil antitrust action seeking treble damages and injunctive and other equitable relief arising out of Defendants’ unlawful exclusion of generic competition from the market for modafinil, a drug marketed by Cephalon, Inc. (“Cephalon”) as a “wakefulness promoting agent,” and indicated for the treatment of certain sleep disorders, including narcolepsy. Modafinil is sold by Cephalon under the brand name Provigil.

2. As detailed below, Cephalon engineered a conspiracy to restrain trade, and a scheme to monopolize the U.S. market for pharmaceutical products with modafinil as the active ingredient (the “modafinil market”), by substantially delaying the onset of generic competition for its top selling drug, Provigil. Among other aspects of its exclusionary scheme, Cephalon entered into agreements with its prospective generic competitors Teva Pharmaceuticals Industries, Ltd. (“Teva”), Barr Laboratories, Inc. (“Barr”), Mylan Laboratories, Inc. (“Mylan”), and Ranbaxy

Laboratories, Inc. (“Ranbaxy”) (collectively the Generic Defendants”), whereby Cephalon agreed to pay the Generic Defendants a total of up to \$136 million, as well as provide other compensation, in exchange for agreements by the Generic Defendants not to sell their generic versions of Provigil until October 2011 (or April 2012, if Cephalon obtained a six-month pediatric exclusivity extension).

3. Generic versions of brand name drugs contain the same active ingredient, and are found by the FDA to be just as safe and effective, as their brand name counterparts. The only material difference between generics and brand name drugs is their price -- generics are typically at least 30% less expensive than their brand counterparts when there is a single generic competitor; this discount typically increases to 50-80% (or more) when there are multiple generic competitors on the market. As a result, generics constitute both: (a) an opportunity for drug purchasers and consumers to obtain enormous cost savings; and (b) a serious threat to the monopoly power and profits of the manufacturer of the brand name drug facing generic competition. Indeed, AB-rated generic versions of brand name drugs typically take 80% or more of the sales of a drug molecule from the brand name product within a year of generic entry.

4. Acutely aware of these economic realities of the pharmaceutical industry, Cephalon engineered a scheme whereby it would, *inter alia*: (a) make significant payments to the Generic Defendants in exchange for their agreements to refrain from selling their less expensive generic versions of Provigil until either 2011 or 2012 (*i.e.*, for up to at least 6½ years); and (b) disguise these “exclusion payments” as payments for: (i) licenses and/or supply agreements regarding modafinil (regarding Teva, Barr and Ranbaxy); or (ii) product development agreements for unrelated products (regarding Mylan). Defendants intentionally concealed the true purpose and

nature of these exclusion payments in an attempt to shield their exclusionary agreement from antitrust scrutiny.

5. Cephalon knew that its patent infringement claims against the Generic Defendants were weak, and thus, under applicable patent law, it could not use its patent to obtain a court order excluding the Generic Defendants from coming to market after Cephalon's Orphan Drug Exclusivity expired on December 24, 2005. That is why in November 2005, prior to paying the Generic Defendants to stay off the market until at least 2011, Cephalon, in giving guidance to securities analysts regarding its forecasted sales and earnings for 2006, expressly stated that it expected generic competition for Provigil in 2006. After executing the exclusionary agreements with the Generic Defendants, however, Cephalon immediately and significantly increased its projected sales and earnings for 2006 because it knew that the agreements precluded competition from the Generic Defendants until at least 2011.

6. Absent the illegal agreements not to compete with the Generic Defendants, generic competition for sale of modafinil would have commenced in or about June 2006, and Plaintiffs and other end-payors of modafinil would have been able to purchase modafinil at significantly lower prices than they were forced to pay because of Defendants' illegal acts to delay generic competition.

7. As a result of their illegal scheme, Defendants: (1) illegally maintained Cephalon's monopoly power in the market for modafinil in the United States; (2) fixed, raised, maintained, and/or stabilized the price of modafinil at supra-competitive levels; and (3) overcharged Plaintiffs and other end-payors of Provigil from Cephalon by millions of dollars by depriving them of the results of competition from cheaper generic versions of Provigil.

8. Defendants' "exclusion payment" agreements constitute horizontal market allocation agreements, which are *per se* violations of Section 1 of the Sherman Act and analogous state laws. Defendants' conduct also constitutes a conspiracy to restrain trade, in violation of Section 1 of the Sherman Act and analogous state laws.

9. Similarly, as alleged in more detail below, Defendants violated Section 2 of the Sherman Act and analogous state laws through their scheme to improperly maintain and extend Cephalon's monopoly power by foreclosing or delaying competition from lower-priced generic versions of Provigil.

10. Cephalon's monopoly power in the modafinil market was maintained through willful, exclusionary conduct, as distinguished from growth or development as a consequence of a legally obtained valid patent, other legally obtained market exclusivity, a superior product, business acumen or historic accident.

#### **JURISDICTION AND VENUE**

11. The Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337(a) and 15 U.S.C. §§ 22 and 26. In addition, this Court has jurisdiction over the state law claims pursuant to 28 U.S.C. § 1332(d), as amended in 2005, and 28 U.S.C. § 1367.

12. Venue is proper in this District under 15 U.S.C. § 22, and under 28 U.S.C. §§ 1391(b) and (c), 28 U.S.C. § 1407, because: (1) Defendants transact business and are found within this District; and (2) a substantial portion of the affected trade and commerce described below has been carried out in this District.

## **THE PARTIES**

### **A. PLAINTIFFS**

13. Plaintiff Vista Healthplan, Inc. (“Vista”), a Florida corporation, is a health benefits company with its principal place of business in Sunrise, Florida. Vista pays some or all of the costs of prescription drugs dispensed, including Provigil, to its members.

14. Plaintiff Pennsylvania Turnpike Commission (“PTC” or the “Commission”) was created in 1937 by the Pennsylvania Legislature, Act 211. PTC, in its capacity to construct, finance, operate and maintain the Pennsylvania Turnpike, oversees 26 maintenance facilities as well as numerous collection facilities and service plazas. The Commission employs over 2,000 people and provides medical benefits for eligible employees. During the Class Period as described herein, the PTC has paid for some or all of the purchase price of Provigil prescribed to one or more of its participants or beneficiaries during the Class Period and has thereby been injured, and continues to be injured, as a result of Defendants’ conduct.

15. Plaintiff Debra Langan is a resident of New York and a purchaser, during the class period described below, of Provigil.

16. Plaintiff Pennsylvania Employees Benefit Trust Fund (“PEBTF”) is a labor-management trust fund duly organized under the laws of the Commonwealth of Pennsylvania, with its principal place of business at 150 South 43rd Street, Suite 1, Harrisburg, Pennsylvania 17111-5700. The Fund provides comprehensive healthcare benefits, including prescription drug coverage, to over 270,000 participants and beneficiaries, which includes active and retired employees of the Commonwealth of Pennsylvania and their spouses and dependents. Participants and beneficiaries of the Fund live in Pennsylvania and a number of other states. During the Class Period as described herein, the Fund has paid for some or all of the purchase price of Provigil

prescribed to one or more of its participants or beneficiaries during the Class Period, and has thereby been injured, and continues to be injured, as a result of Defendants' conduct.

17. Plaintiff District Council 37 Health & Security Plan is a public sector union-sponsored employee welfare benefit plan, which provides a prescription drug benefit for covered titles, retirees and their spouses and dependants. Contributions towards such benefits are bargained for with various municipal employers, including The City of New York, various authorities and corporations and quasi-public institutions. DC 37 is a legal entity entitled to bring suit in its own name pursuant to 29 U.S.C. § 1132(d). DC 37 maintains its principal place of business in New York, New York. It provides supplemental health benefits, including a prescription drug benefit for over 270,000 participants and beneficiaries in all but one state in the U.S. During the Class Period, DC 37, through its prescription drug benefit manager, has been billed for and paid charges for Provigil used by its participants and beneficiaries, and has thereby been harmed.

## **B. DEFENDANTS**

18. Defendant Cephalon is a company incorporated under the laws of the State of Delaware, with its principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355. Cephalon develops, manufactures, and markets pharmaceuticals and related products in the United States.

19. Defendant Barr is a company incorporated under the laws of the State of New York, with its principal place of business at Two Quaker Road, Pomona, New York 10970. Barr principally develops, manufactures and markets generic versions of brand name drugs.

20. Defendant Mylan is a company incorporated under the laws of the Commonwealth of Pennsylvania, with its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. Mylan's subsidiary, Mylan Pharmaceuticals, Inc., is located at 781 Chestnut



Ridge Road, Morgantown, West Virginia 26505. Mylan principally develops, manufactures and markets generic versions of brand name drugs.

21. Defendant Teva Pharmaceutical Industries, Ltd. is an Israeli company. Teva Pharmaceuticals USA, Inc., a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd., is a company incorporated under the laws of the State of Delaware, with its principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454. Collectively, the defendant corporations identified in this paragraph are referred to herein as Teva. Teva principally develops, manufactures and markets generic versions of brand name drugs.

22. Defendant Ranbaxy Laboratories, Ltd. is a company operating under the laws of India. Ranbaxy Pharmaceuticals, Inc., a wholly-owned subsidiary of Ranbaxy Laboratories, Ltd., with its principal place of business located at 600 College Road East, Suite 2108, Princeton, New Jersey 08540. Collectively, the defendant corporations identified in this paragraph are referred to herein as Ranbaxy. Ranbaxy principally develops, manufactures and markets generic versions of brand name drugs.

### **CLASS ACTION ALLEGATIONS**

23. Plaintiffs bring this action on behalf of themselves and as representatives of a Class defined as follows:

All persons or entities throughout the United States and its territories who purchased and/or paid for Provigil or generic versions of Provigil for consumption by themselves, their families, or their members, employees, insureds, participants or beneficiaries (the “Class”) during the period from June 2006 through the date on which the anti-competitive effects of Defendants’ conduct cease (“the Class Period”).

For purposes of the Class definition, persons and entities “purchased” Provigil if they paid some or all of the purchase price. Excluded from the Class are all Defendants, their officers, subsidiaries and

affiliates; the judge and his immediate family; all government entities (except for government-funded employee benefit plans); and all persons or entities that purchased Provigil for purposes of resale, or directly from any of the Defendants or their affiliates.

24. Plaintiffs seek class certification pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure as to declaratory and equitable relief sought herein, and Rule 23(b)(3) as to the damages sought herein.

25. Although Plaintiffs do not know the exact number of Class members, it believes it to be, at a minimum, in the tens of thousands. Thus, members of the Class are numerous and joinder is impracticable. The Class members are identifiable, *inter alia*, from information and records that are required by law to be maintained by pharmacies, drugstores, pharmaceutical benefits managers, and managed care organizations

26. Plaintiffs' claims are typical of the claims of the members of the Class. Plaintiffs and all members of the Class were damaged by the same wrongful conduct by Defendants, *i.e.*, they paid artificially inflated prices for Provigil and were deprived of the benefits of competition from cheaper generic versions of Provigil as a result of Defendants' wrongful conduct.

27. Plaintiffs will fairly and adequately protect and represent the interests of the Class. Plaintiffs' interests are coincident with, and not antagonistic to, those of the Class.

28. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigation in the pharmaceutical industry.

29. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual Class members because Defendants have acted



on grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

30. Questions of law and fact common to the Class include:

- (a) whether Defendants' agreements constitute illegal market allocation agreements;
- (b) whether Defendants maintained Cephalon's monopoly power by delaying generic entry;
- (c) whether direct proof of Defendants' monopoly power is available, and if available, whether it is sufficient to prove Defendants' monopoly power without the need to also define a relevant market;
- (d) to the extent a relevant market or markets must be defined, what that definition is or those definitions are;
- (e) whether the activities of Defendants as alleged herein have substantially affected interstate commerce; and
- (f) whether, and to what extent, Defendants' conduct caused antitrust injury, and if so, the appropriate measure of damages.

31. Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

32. Plaintiffs know of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

### **FACTUAL ALLEGATIONS**

33. The manufacture, marketing, distribution, and sale of prescription drugs is one of the most profitable industries in the United States. The U.S. market accounts for more than 40% of the world's prescription pharmaceutical revenues. The cost of prescription drugs in the United States has been rising at a rate of 14% to 18% per year. In 1997, over \$97 billion worth of prescription drugs were dispensed in the United States alone. By 2001, the cost of drugs dispensed in the United States was approximately \$160 billion.

34. To stem the rising cost of prescription drugs, Congress in 1984 amended the Food, Drug, and Cosmetic Act by adding the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. *See* Pub.L.No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S. §355 and 35 U.S.C. §271(e)). As more fully explained below, the Hatch-Waxman Amendments were designed to bring less expensive generic drugs to market faster. However, in contravention of this expressed goal, Defendants used the Hatch-Waxman Amendments to unlawfully prevent generic entry into the market and illegally maintain their Provigil monopoly.

#### **A. THE REGULATORY STRUCTURE PURSUANT TO WHICH GENERIC SUBSTITUTES FOR BRAND NAME DRUGS ARE APPROVED**

35. Under the Federal Food, Drug, and Cosmetics Act (21 U.S.C. §§ 301-392), manufacturers who create a new, pioneer drug must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.

36. Hatch-Waxman simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file a lengthy and costly NDA in order to obtain FDA

approval. Instead, the FDA provides an expedited review process by which generic manufacturers may file an Abbreviated New Drug Application (“ANDA”).

37. The ANDA relies on the scientific findings of safety and effectiveness included by the brand name drug manufacturer in the original NDA. The ANDA filer must demonstrate to the FDA that the generic drug it proposes to market is bioequivalent to the brand name drug.

38. As a counter-balance to this abbreviated process for bio-equivalent generic drugs, Hatch-Waxman streamlined the process for a brand name manufacturer to enforce its patents against infringement by generic manufacturers, and provided that, under certain conditions (as detailed below), the FDA could not grant a generic manufacturer final approval to market or sell a generic version of the brand name drug for up to 30 months.

39. When the FDA approves a brand name manufacturer’s NDA, the FDA publishes any compound patents which (according to the brand name manufacturer) claim the approved drug in a publication entitled the “Approved Drug Products with Therapeutic Equivalence Evaluations,” known as the “Orange Book.” 21 U.S.C. § 355(j)(7)(A)(iii). In the case of method of use patents, the FDA lists in the Orange Book any patents which (according to the brand name manufacturer) claim the approved drug for its approved method of use. In listing patents in the Orange Book, the FDA merely performs a ministerial act. The FDA does not check the facts supplied to it by the brand name manufacturer, but trusts that the manufacturer will be truthful. After the NDA is approved, the brand name manufacturer may list other new patents in the Orange Book as related to the NDA, if the brand name manufacturer similarly certifies, *inter alia*, that the new patents claim either the approved drug (for compound patents) or that the patents claim the approved drug for approved methods of use (for method-of-use patents).

40. To obtain FDA approval of an ANDA (and thus the right to sell a generic version of a brand name drug), a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications:

- (a) that no patent for the brand name drug has been filed with the FDA (a "Paragraph I certification");
- (b) that the patent for the brand name drug has expired (a "Paragraph II certification");
- (c) that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or
- (d) that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

21 U.S.C. § 355(j)(2)(A)(vii).

41. If a generic manufacturer files only paragraph I, II, or III certifications, then it is able to take advantage of the expedited Hatch-Waxman approval process, and the FDA must act on the application within 180 days of receipt, unless both the FDA and the applicant agree to extend the deadline. 21 U.S.C. § 355(j)(5)(A).

42. If a generic manufacturer files a Paragraph IV certification claiming that a patent listed in the Orange Book is invalid or will not be infringed, a brand name manufacturer has an opportunity to delay the final FDA approval of the ANDA and the sale of the competing generic drug on the market. When a generic drug manufacturer files a Paragraph IV certification with its ANDA, the generic manufacturer must promptly give notice of its certification to both the NDA-holder and the owner of the patent(s) at issue. If the NDA-holder initiates a patent infringement action against the ANDA filer within 45 days of receiving the Paragraph IV certification, then the FDA may not grant final approval to the ANDA until the earlier of either: (a) 30 months from the

date the ANDA is filed; or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). Thus, by listing a patent in the Orange Book and filing a suit within 45 days of receiving a Paragraph IV certification regarding the listed patent, a brand name drug manufacturer may delay when the generic drug is finally approved by the FDA, and when generic competition to the brand name drug enters the market. During the pendency of the 30 month stay, the FDA may grant "tentative approval" to an ANDA applicant if the FDA determines that the ANDA would otherwise qualify for final approval but for the stay.

43. Because of the FDA rules alleged above, brand name manufacturers have an incentive to: (a) list patents in the Orange Book, even if such patents are not eligible for listing; and (b) then sue any generic competitor that files an ANDA with paragraph IV certifications, even if such competitor's product does not actually infringe the listed patent(s), in order to delay final FDA approval of an ANDA for up to 30 months. In addition, prior to a recent change in the Hatch-Waxman regulations, brand companies could, and did, bring multiple infringement suits (based on multiple patents listed in the Orange Book) against a single ANDA, thereby obtaining independent 30-month stays associated with each suit. This practice was curtailed by a change in FDA regulations mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which, due to repeated abuses by brand manufacturers of the type described here, limited brand manufacturers to a single stay per ANDA. *See* 21 C.F.R. §§ 314.52, 314.95, 314.107(b)(3)(i)(A).

44. Hatch-Waxman also provides brand name manufacturers with other opportunities to obtain protection from generic competition. For example, if the FDA approves an NDA involving a new chemical entity (NCE), the brand manufacturer filing the NDA may obtain five years of

exclusivity from the date of approval of the NDA. In addition, if an NDA drug treats a rare condition, FDA may, if appropriate, grant an additional two years of Orphan Drug exclusivity.

45. As detailed below, Cephalon sought and obtained both NCE and Orphan Drug exclusivity for Provigil. These exclusivities expired on December 24, 2003 and December 24, 2005, respectively.

**B. GENERIC VERSIONS OF BRAND NAME DRUGS ARE SIGNIFICANTLY LESS EXPENSIVE, AND TAKE SIGNIFICANT SALES DIRECTLY FROM THE CORRESPONDING BRAND NAME VERSIONS**

46. Drugs proven to meet bioequivalence requirements through *in vivo* (clinical) and/or *in vitro* (laboratory) testing receive an “AB” rating from the FDA. In order to be approved as an AB-rated product by the FDA, a drug must have the same dose as the brand drug, the same route of administration (i.e., oral, intravenous), and the same dosage form as the brand name.

47. Typically, AB-rated generic versions of brand name drugs are priced significantly below the brand name versions and generate large savings for consumers. A 1998 Congressional Budget Office Report estimated that in 1994 alone, purchasers saved \$8 to \$10 billion on prescriptions at retail pharmacies by purchasing generic drugs instead of the equivalent branded drugs. A 2004 FDA study calculates that patients could reduce the daily costs of their medications by more than 50% by purchasing generic drugs when available. According to the National Association of Chain Drug Stores, the average retail price for a brand-name prescription was about \$111 in 2006, while the average retail price for a generic prescription was just over \$32.

48. The price differentials between the branded product and the AB-rated generic drug, as well as other institutional features of the pharmaceutical market, cause generic versions to be rapidly and substantially substituted for their brand name counterparts. In every state, pharmacists are permitted (and, in most states, required) to substitute an AB-rated generic product for a brand



name product unless the doctor has indicated that the prescription for the brand name product must be dispensed as written. As more generic manufacturers enter the market, prices for generic versions of a drug predictably decrease even further because of competition among the generic manufacturers, and the loss of sales volume by the brand name drug to the corresponding generic accelerates.

49. An AB rating is particularly significant to a generic manufacturer because, under the statutory regime enacted by both Congress (*i.e.*, Hatch-Waxman ) and most state legislatures (which enacted Drug Product Selection, or DPS laws), pharmacists may substitute an AB-rated generic version of a drug for the brand name without seeking or obtaining permission from the prescribing doctor (unless the prescription is denominated “Dispense as Written,” or DAW). Indeed, both Congress and the state legislatures have actively encouraged generic substitution because of their recognition that the economics of the pharmaceutical industry prevent generic manufacturers from simultaneously: (a) engaging in the type of heavy promotion or “detailing” typically done by brand name manufacturers; and (b) providing the enormous cost savings to purchasers and consumers generated by generic drugs.

50. Generic competition enables all members of the proposed Class to: (a) purchase generic versions of the drug at substantially lower prices; and/or (b) purchase the brand name drug at a reduced price. However, until a generic manufacturer enters the market, there is no bioequivalent generic drug which competes with the brand name drug, and therefore, the brand name manufacturer can continue to charge supracompetitive prices profitably without losing all or a substantial portion of its brand name sales. Consequently, brand name drug manufacturers have a strong interest to use the tactics alleged above to delay the introduction of generic competition into the market.

51. The Hatch Waxman Act also rewards the first generic to file an ANDA with a Paragraph IV certification with 180 days of marketing exclusivity upon the advent of generic competition., *see* 21 U.S.C. §355(j)(2)(A)(vii). During that time, no other generic is allowed by the FDA to enter with an AB-rated version of the same drug.

52. However, where (as here), multiple generic companies file ANDA associated with Paragraph IV certifications on the same day, the FDA has ruled that each of the companies is entitled to launch its generic during the 180 day period, and the exclusivity is shared. *See Guidance for Industry on 180-Day Exclusivity When Multiple Abbreviated New Drug Applications Are Submitted on the Same Day*, 68 Fed. Reg. 45252, 45255 (Aug. 1, 2003). Defendant Mylan explains that this means that the usual advantage to a first filer may be lost “where we are required to share our exclusivity period with other ANDA sponsors with Paragraph IV certifications” because faces a “material adverse effect on our ability to market that product profitably and on our financial position and results of operations, and the market value of our common stock could decline.” Mylan Laboratories, Inc., Form 10-Q, at 22 (Nov. 4, 2005).

### **C. PROVIGIL**

53. Provigil is a brand name drug manufactured by Cephalon. Provigil is marketed as a “wakefulness promoting agent” and is used in the treatment of certain sleep disorders, including narcolepsy and shift work sleep disorder. The active pharmaceutical ingredient in Provigil is modafinil.

54. Modafinil is a psychostimulant that enhances wakefulness and vigilance but its pharmacological profile, and thus its side effect and efficiency profile, is significantly different than drugs such as amphetamines and methylphenidate (Ritalin). These drugs are not AB-rated to Provigil, and are not reasonably interchangeable with modafinil.

55. The FDA approved Cephalon's NDA for Provigil on December 24, 1998, and Cephalon began selling Provigil shortly thereafter. Because modafinil constituted a new chemical entity (NCE), Cephalon received five years of NCE exclusivity. Provigil's NCE exclusivity expired on December 24, 2003.

56. Likewise, because Cephalon represented to the FDA that modafinil was a drug to treat a rare disorder (narcolepsy), Cephalon received Orphan Drug exclusivity, which expired on December 24, 2005.

57. In anticipation of the expiration of Provigil's NCE and/or Orphan Drug exclusivities, each of the Generic Defendants developed, and filed an ANDA seeking FDA approval for, AB-rated generic versions of Provigil. Each Generic Defendant filed its ANDA on December 24, 2002, the first day that ANDAs for generic version of Provigil could be filed under the NCE provisions of Hatch-Waxman.

58. Thus, given the FDA's interpretation of applicable law, the Generic Defendants could share 180-day exclusivity because they all filed ANDAs on the same day. This meant that if the FDA approved their products, all Generic Defendants could simultaneously market generic products during the 180-day exclusivity period. It also meant that if one Generic Defendant should market its drug before the other Generic Defendants did so, the 180-day exclusivity period *for all of the Generic Defendants* would then begin to run. *See Guidance for Industry on 180-Day Exclusivity When Multiple Abbreviated New Drug Applications Are Submitted on the Same Day*, 68 Fed. Reg. 45252, 45255 (Aug. 1, 2003).

59. Each of the Generic Defendants received tentative approval from the FDA for its generic version of Provigil prior to December 24, 2005, the date that Orphan Drug exclusivity for Provigil expired--Barr on January 7, 2004; Ranbaxy on February 18, 2004; Mylan on February 9,

2005; and Teva on December 16, 2005. “Tentative approval” means that an ANDA is deemed by FDA to be safe, effective and bioequivalent to its brand name counterpart, but the existence of some legal or regulatory barrier (such as Orphan Drug exclusivity) precludes the FDA from granting final approval to sell the generic product at issue.

60. As detailed further below, absent Defendants’ wrongful and exclusionary conduct, each of the Generic Defendants would have obtained final FDA approval, and would have begun selling its generic version of Provigil--at prices significantly below the price of brand name Provigil--on or shortly after the expiration of Provigil’s Orphan Drug exclusivity on December 24, 2005.

#### **D. CEPHALON’S PROVIGIL PATENT**

61. The drug substance modafinil is an acetamide derivative. Both the compound modafinil and its neuropsychopharmacological profile have been known since at least the late 1980s.

62. On October 6, 1994, Cephalon scientists Peter Grebow, Vincent Corvari, and David Stong filed United States Application Serial No. 08/319,124 (“the ‘124 Application”) titled “Acetamide Derivative Having Defined Particle Size” with the United States Patent & Trademark Office (“PTO”). Because the compound modafinil was prior art, the ‘124 Application could not validly claim broadly the compound modafinil. Instead, the ‘124 Application narrowly claimed very specific formulations of modafinil, as well as certain uses of those narrow formulations.

63. In conjunction with filing the ‘124 Application, the named inventors (*i.e.*, Grebow, Corvari and Stong) assigned their interests to Cephalon and submitted declarations acknowledging their duty of candor (*i.e.*, the duty to disclose all material information) to the PTO and affirming that they were the true and properly named inventors for the ‘124 Application. This duty of candor extended to all named inventors, as well as to others such as patent attorneys and

declarants substantively involved in the prosecution of the '124 Application. On April 8, 1997, the '124 Application issued as United States Patent No. 5,618,845 ("the '845 Patent").

64. On December 27, 1996, Cephalon filed new drug application no. 20-717 ("NDA No. 20-717") with the Food & Drug Administration ("FDA") seeking to market 100mg and 200mg strengths of modafinil under the brand name Provigil for the treatment of narcolepsy. On December 24, 1998, FDA approved NDA No. 20-717. Shortly thereafter, Cephalon began commercially marketing Provigil.

65. On or before April 1, 1999, Cephalon concluded that the '845 Patent was wholly or partly inoperative or invalid. Seeking to remedy perceived defects in the '845 Patent, Cephalon filed a reissue application ("the RE '166 Application"). The filing of the RE '166 Application triggered new duties of candor for those individuals substantively involved in the prosecution of the RE '166 Application. On January 15, 2002, the PTO issued reissue patent no. 37,516 ("the RE '516 Patent") and Cephalon surrendered the '845 Patent.

66. On or about February 12, 2003, Mylan notified Cephalon that it had filed ANDA No. 76-594 seeking to market generic versions of Provigil containing 100mg and 200mg of modafinil, the active ingredient in Provigil. Mylan's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic product would not infringe any valid claim of the RE '516 Patent.

67. On or about February 20, 2003, Barr notified Cephalon that it had filed ANDA No. 76-597 seeking to market generic versions of Provigil containing 100mg and 200mg of modafinil. Barr's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic product would not infringe any valid and enforceable claim of the RE '516 Patent.



68. On or about February 25, 2003, Teva notified Cephalon that it had filed ANDA No. 76-596 seeking to market generic versions of Provigil containing 100mg and 200mg of modafinil. Teva's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic product would not infringe any valid and enforceable claim of the RE '516 Patent.

69. On or about March 21, 2003, Ranbaxy notified Cephalon that it had filed ANDA No. 76-595 seeking to market generic versions of Provigil containing 100mg and 200mg of modafinil. Ranbaxy's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic product would not infringe any valid claim of the RE '516 Patent.

70. On March 28, 2003, Cephalon filed suit in the United States District Court for the District of New Jersey alleging infringement of the RE '516 Patent by the Generic Defendants.

71. During discovery, as recited immediately below, the Generic Defendants uncovered facts supporting a host of defenses that cast serious doubt on: (1) the enforceability of the RE '516 Patent; (2) the validity of its claims; and (3) the strength of Cephalon's infringement theory.

72. For example, despite representations, declarations and/or suggestions to the contrary, the modafinil compositions and methods claimed in the '845 Patent and the RE '516 Patent (collectively the "Cephalon Patents") were manufactured and developed by scientists at Laboratoire L. Lafon ("Lafon"), rather than scientists at Cephalon. Neither the named inventors of the '845 Patent nor the prosecuting attorneys informed the PTO about this material information during the prosecution of the '845 Patent. To the contrary, this material information was intentionally withheld from the PTO. During the prosecution of the RE '516 Patent, Cephalon agents with a duty of candor had another opportunity to properly disclose these facts, but again intentionally declined to do so.



73. The named inventors and prosecuting attorneys similarly did not inform the PTO that Lafon sold and delivered modafinil tablets to Cephalon prior to the Cephalon Patents' critical date of October 6, 1993 under a Supply Agreement and a License Agreement executed in January of 1993. The modafinil tablets and modafinil active pharmaceutical ingredient ("API") sold and delivered to Cephalon prior to the critical date fall within some, if not all, of the composition claims recited in the Cephalon Patents. The sale and delivery of modafinil tablets and modafinil API under the Supply Agreement were highly material to patentability and were intentionally withheld by individuals substantively involved in the prosecution of the '845 Patent. During the prosecution of the RE '516 Patent, Cephalon agents with a duty of candor had another opportunity to properly disclose these facts, but again intentionally declined to do so.

74. The named inventors and/or prosecuting attorneys for the Cephalon Patents intentionally misrepresented in the patent specification, and in Peter Grebow's September 26, 1995 declaration, that certain domestic and foreign clinical trials had followed the same protocol. In fact, the foreign clinical trial conducted by Lafon administered half of the daily dose of modafinil in each of two daily doses whereas the domestic clinical trial conducted by Cephalon administered the entire daily dose in a single dose. During patent prosecution, Cephalon relied upon the existence of purported differences in adverse effects in the domestic and foreign trials in support of patentability, without telling the Examiner about the critical protocol change. The protocol change was material in part because it offered an explanation for the alleged adverse effects different than the explanation advanced by Cephalon in support of patentability. During the prosecution of the RE '516 Patent, Cephalon agents with a duty of candor had another opportunity to properly disclose these facts, but again intentionally declined to do so.

75. The inventors and their attorneys misrepresented to the PTO in the Cephalon Patents specification that the adverse events observed in the domestic clinical trial at 800 mg doses were completely unexpected. Peter Grebow, a named inventor, further misled the PTO when he reiterated that contention in his September 26, 1995 declaration in support of patentability. In reality, Lafon informed Cephalon in February of 1993 that a single 600 mg dose of modafinil may cause adverse effects, a fact specifically known to Peter Grebow. Furthermore, the named inventors report in the specification that no clinically significant adverse events occurred in the foreign clinical trials conducted by Lafon. In fact, numerous serious adverse events were observed during those foreign clinical trials. Peter Grebow was aware of those instances of adverse events and even forwarded Lafon's "serious adverse event" information to a Canadian counterpart.

76. The named inventors and prosecuting attorneys at Cephalon also intentionally concealed from the PTO that the domestic clinical trial described in the Cephalon Patents, which used modafinil compositions covered by at least one of the composition claims, and which followed the method of administration falling within at least one of the method claims, occurred prior to both the critical date and the alleged conception date. The subjects of the first United States clinical trial were members of the public, and they were under no obligation of confidentiality to Cephalon or the clinical investigators. The non-confidential, public clinical trial was material to patentability. During the prosecution of the RE '516 Patent, Cephalon agents with a duty of candor had another opportunity to properly disclose these facts, but again intentionally declined to do so.

77. The named inventors and prosecuting attorneys also intentionally misrepresented to the PTO that the dog plasma level data discussed in the Cephalon Patents demonstrated that the claimed small particle modafinil compositions result in higher peak plasma levels than the large

particle modafinil compositions of the prior art. Notwithstanding their representations to the PTO, the named inventors and prosecuting attorneys knew that the test results were not statistically significant. Indeed, the contrary was true. Cephalon's DM-93-014 report to the FDA includes representations directly contradictory to those made to the PTO. That report, completed at least as early as November 8, 1996 (*i.e.*, while the '845 Patent was still pending and before the RE '516 Patent was filed), concluded that there was no statistically significant difference in the peak plasma levels as a function of modafinil particle size. Cephalon agents with a duty of candor intentionally withheld the FDA report and the contradictory representations therein from the PTO during prosecution of the '845 Patent. During the prosecution of the RE '516 Patent, Cephalon agents with a duty of candor had another opportunity to properly disclose these facts, but again intentionally declined to do so.

78. The named inventors and/or prosecuting attorneys also intentionally withheld the fact that Lafon had already considered the importance of maintaining particle size controls over modafinil drug product prior to Cephalon's alleged invention. Lafon provided Cephalon with particle size information for all of the lots of modafinil API Lafon sold and delivered to Cephalon, including API Lot 003. The Cephalon Patents give the false impression that Cephalon was the first to measure particle size for modafinil and the first to recognize the importance of particle size. The named inventors and their attorneys also misrepresented to the PTO that one or more of the named inventors had discovered that the dissolution rate of modafinil increases with a decrease in particle size. In fact, Lafon scientists discovered the relationship between modafinil dissolution rate and particle size in 1989. Moreover, Lafon had communicated the relevant dissolution and particle size data to Cephalon in March of 1993. In addition, Peter Grebow represented to the PTO that there were no publications suggesting that the utility of modafinil could be improved by

reducing its particle size when in fact he knew of a document published in September of 1993, more than one year prior to the filing date, which suggests that modafinil bioavailability differences may be caused by the particle size distribution. These misrepresentations and omissions were material to patentability. During the prosecution of the RE '516 Patent, Cephalon agents with a duty of candor had another opportunity to properly disclose these facts, but again intentionally declined to do so.

79. In February 2005, the Generic Defendants filed amended answers alleging in detail the facts above supporting their inequitable conduct defenses and counterclaims. Many of these same facts supported a finding that some or all of the claims of the RE '516 Patent were invalid.

80. Based on the facts and circumstances alleged above, in August and September 2005, the Generic Defendants filed a series of motions seeking summary judgment that some or all of the claims of the RE '516 patent were invalid, as a matter of law. Those motions were fully briefed as of November 14, 2005.

81. Moreover, the Generic Defendants argued, in summary judgment motions filed with the patent court under Fed. R. Civ. P. 11, that their evidence of non-infringement was so clear and strong that the Generic Defendants were entitled to a finding, as a matter of law, that their generic products did not infringe the RE '516 Patent. (Most of the information relevant to these non-infringement claims is not publicly available.)

82. Starting in December 2005, Cephalon began settling its claims against the Generic Defendants. Each settlement culminated in a dismissal with prejudice, thereby allowing Cephalon to avoid a judicial resolution of the defenses the Generic Defendants had raised.

83. As a result of the facts and circumstances detailed above, each of the Defendants knew (or should have known) that, because Cephalon's patent claims were weak, and the Generic



Defendants' patent defenses were strong, that absent settlements, it was highly likely that Cephalon would have lost the patent litigations involving Provigil on the merits.

**E. CEPHALON'S PLAN TO DELAY GENERIC COMPETITION**

84. Cephalon began selling modafinil, under the brand name Provigil in December 1998. Cephalon was the only company permitted to sell modafinil from December 1998 through December 2005--first, because it obtained five years of NCE exclusivity (which expired in December 2003), and then because it obtained two additional years of Orphan Drug exclusivity (which expired in December 2005).

85. Despite the fact that Cephalon received the two years of Orphan Drug exclusivity by representing to the FDA that Provigil was a niche drug used to treat a rare disorder (and thus supposedly had a limited potential market), sales of Provigil grew substantially, exceeding \$800 million in 2008 and representing over 46% of Cephalon's total sales. Federal and state governments investigated whether Cephalon improperly inflated its Provigil sales by illegally promoting or marketing Provigil for uses other than the limited/specific uses approved by the FDA -- *i.e.*, for "off label" uses. As a result of the government findings, Cephalon agreed to a plea agreement and paid \$425 million as part of a comprehensive settlement of the federal and state claims.

86. Prior to December 2005, Cephalon recognized the likelihood that, despite the existence of its patent and its patent suits against the Generic Defendants, Cephalon would lose its modafinil monopoly at or about the time that its Orphan Drug exclusivity expired on December 24, 2005. There are several reasons why Cephalon knew before December 2005 that generic competition was imminent. First, three of the Generic Defendants had obtained tentative approval of their ANDAs for their generic versions of Provigil by January 2005. (The fourth Generic Defendant,

Teva, received tentative approval on December 16, 2005.) As explained above, tentative approval means that: (a) the FDA has determined that the generic product is safe, effective and bioequivalent to its brand name counterpart; and (b) the only barrier to the grant of final approval to sell the generic product is the existence of some form of legal or regulatory exclusivity--such as Orphan Drug exclusivity.

87. Since Cephalon knew that its Orphan Drug exclusivity was set to expire on December 24, 2005, it also knew that, if it did nothing: (a) the Generic Defendants were likely to obtain final approval of their ANDAs, and come to market with their generic versions of Provigil, on or shortly after December 24, 2005; and (b) Cephalon would quickly lose the vast majority of its Provigil sales, as purchasers would switch most of their modafinil purchases to the bioequivalent--but substantially less expensive--generic versions of Provigil.

88. Second, Cephalon knew that its RE '516 Patent would not preclude the Generic Defendants from coming to market on or shortly after December 24, 2005 because: (a) the 30 month stays, automatically obtained by Cephalon merely by filing their meritless patent suits against the Generic Defendants (within 45 days of receipt of the generics' Paragraph IV Certifications), expired by no later than September 2005; (b) Cephalon's patent did not give it an automatic right to exclude its generic competitors, but rather a right to try to use its patent to obtain a court order excluding or enjoining generic competition; and (c) under controlling patent law, Cephalon would have been required to establish, *inter alia*, that it was likely to succeed on the merits of the underlying suit in order to obtain an injunction order to keep the Generic Defendants off the market after expiration of the 30 month stay. However, the weakness of Cephalon's patent claims, and the strength of the patent defenses raised by Generic Defendants in the underlying patent cases, precluded Cephalon from obtaining a court order enjoining generic



competition. In fact, as detailed above, Cephalon could not have established a likelihood of success on the merits, because it was highly likely that, but for the settlements, Cephalon would have lost the patent cases on the merits.

89. Indeed, Cephalon management was so convinced that generic competition was imminent prior to December 2005 that they informed the investment community in November 2005 that Cephalon was projecting a substantial reduction of sales of Provigil in 2006, specifically because it expected generic competition to emerge in 2006.

90. All four Generic Defendants shared this conviction, preparing internal projections that assumed a June 2006 launch date and engaging in plans for a generic launch. For example, Barr, which believed an even earlier launch was possible, ordered substantial quantities of active ingredient from its supplier in late 2005.

91. Moreover, and significantly, Cephalon management also told securities analysts in November 2005 that Cephalon had reduced its promotional spending on Provigil in late 2005 because of its expectation that generic competition would commence promptly. It is common practice in the pharmaceutical industry for brand name manufacturers to reduce detailing for a brand name drug at or shortly before they expect generic competition. Such a reduction in promotion activity makes rational economic sense only if generic competition is expected in the very near future because the reduction in promotion, by itself, could lead to substantially reduced sales and profits for the brand name manufacturer.

92. Third, another tactic employed by Cephalon in light of expected generic competition was to develop, and seek FDA approval, for a new formulation of modafinil, which it called Nuvigil. Nuvigil purportedly has a longer-lasting effect than Provigil. Analysts, however, believed that Nuvigil did not constitute a significant or meaningful improvement over Provigil, but

was simply a vehicle by which Cephalon could attempt to maintain its modafinil sales by attempting to convert demand for modafinil from Provigil, which faced imminent AB-rated generic competition to Nuvigil, which, upon information and belief, would not be AB-rated to--and therefore not readily substitutable for--the existing generic versions of Provigil.

93. From as early as the release of Cephalon's 2003 Annual Report, until the first settlements with the Generic Defendants were announced in December 2005, Cephalon publicly and repeatedly announced its intent to: (a) seek prompt FDA approval of Nuvigil; (b) begin selling Nuvigil upon such approval; and (c) convert the market demand for modafinil from Provigil to Nuvigil, which did not face imminent generic competition. Therefore, Cephalon's plans regarding Nuvigil were well known in the pharmaceutical industry--and thus were known by the Generic Defendants--when the Generic Defendants commenced settlement negotiations with Cephalon.

**F. CEPHALON'S ANTICOMPETITIVE SCHEME TO MAINTAIN ITS PROVIGIL MONOPOLY**

94. Upon information and belief, in late 2005, Cephalon began negotiating settlements of the patent suits with some, if not all, of the Generic Defendants. Cephalon's primary goal in these negotiations was simple--to delay generic competition for Provigil for as long as possible.

95. In order to protect and maintain its monopoly power in the modafinil market, Cephalon would have to induce all of the Generic Defendants to refrain from selling their generic versions of Provigil, because the entry of even a single generic product would quickly cause the majority of modafinil purchases to switch from Cephalon's branded Provigil to the substantially less expensive, but bioequivalent, generic version(s) of Provigil.

96. From the outset of negotiations, Cephalon had decided that it would not agree to generic Provigil entry until three years before the expiration of patent-related exclusivity, in 2011

or 2012 (dependent on whether Cephalon obtained the six-month pediatric exclusivity extension).

This entry date was of limited value to the Generic Defendants, in part because it gave Cephalon a substantial period to switch sales to Provigil's successor product, Nuvigil, and thus significantly reduce potential sales of generic Provigil. The Generic Defendants, who had so aggressively challenged Cephalon's monopoly, were therefore unwilling to settle on this entry date alone without compensation.

97. Because Cephalon was unwilling to compromise on its generic entry date and the Generic Defendants would not agree to Cephalon's date absent other terms, Cephalon had to provide other inducements to the Generic Defendants to secure their agreement to refrain from competing until 2011 or 2012. Cephalon provided these inducements in the form of purportedly independent business transactions--thirteen in all totaling in excess of \$200 million--such as licenses to intellectual property, supply agreements, or co-development deals (collectively "side-term inducements").

98. The side-term inducements that Cephalon provided to the Generic Defendants, however, were not independent business transactions, but were instead inextricably linked with the agreed-upon generic entry date in 2011 or 2012, for at least the following reasons:

- The side-term inducements were entered simultaneously with the associated patent litigation settlements and were often contained in the same document;
- Prior to patent settlement negotiations, Cephalon had no significant discussions with the generic companies regarding the matters covered by the side-term inducements;
- Cephalon did not need licenses to the generic companies' modafinil-related intellectual property to manufacture or sell Provigil or planned successor products; and
- By entering into a series of supply agreements, Cephalon created, in the words of a senior supply manager, a "supply chain nightmare" that makes little sense, absent offsetting consideration in the form of the elimination of potential competition.

99. Cephalon provided an additional incentive to each of the four Generic Defendants to settle by including a “most favored nation” clause in each proposed settlement and by publicizing that provision of each settlement. The clause allowed for accelerated entry by the Generic Defendants in the event that another generic company entered the market. The effect of that clause was to make it less attractive for each successive generic company to continue to litigate or enter at risk because that clause would automatically permit each generic company that had settled to compete without any risk with any non-settling generic company.

100. The purpose and effect of Cephalon’s agreements with the Generic Defendants is to maintain Cephalon’s Provigil monopoly and eliminate potential generic competition to Provigil until 2011 or 2012.

**i. The Teva Settlement**

101. On December 8, 2005, Cephalon reached an agreement to settle its patent litigation with Teva. Under the settlement, Teva must keep its generic version of Provigil off the market until 2011 or 2012 unless another generic manufacturer enters the market prior to that time--in which case Teva would also be permitted to enter.

102. In addition, Teva was to receive up to \$125 million in royalties based on Cephalon’s worldwide sales of Provigil and successor products. Defendants claim the cash payments to Teva were in exchange for: (1) licenses to Teva’s worldwide intellectual property “relating to the manufacture, development and formulation of modafinil”; and (2) “certain agreements with Teva relating to Teva’s manufacture and supply of the active pharmaceutical ingredient (“API”) modafinil.”

103. However, Cephalon did not need a license to Teva’s modafinil-related patent rights. In fact, Cephalon already had all it needed to successfully manufacture and sell Provigil and any



planned successor products, including Nuvigil. Cephalon knew about Teva's patent applications for over three years before it showed interest in a license, and only then because the license was tied to Teva's agreement to refrain from marketing generic Provigil until 2011 or 2012.

104. Furthermore, Cephalon had no need to purchase modafinil from Teva at prices substantially higher than the price Cephalon paid to its existing supplier. At one point, Cephalon even suggested that Teva "forget about API" until after a settlement had been reached. Teva, however, insisted that such a term be included in the settlement, and ultimately Cephalon agreed to a supply term that guarantees Teva a revenue stream until 2011 or 2012, when Teva is permitted to market its generic version of Provigil.

105. The payments to Teva were, in fact, payments to exclude Teva's generic modafinil, based on several factors. First, prior to the settlement, Cephalon had been selling modafinil since February 1999 in the United States, and since 1998 in Europe, without a license under Teva's intellectual property. Thus, Cephalon had no need or use for a license from Teva -- other than to use such a license as a subterfuge to conceal the fact that it was paying Teva not to compete in the modafinil market for up to 6½ years.

106. Second, according to published reports, Cephalon also paid for a supply agreement from Teva for the active ingredient modafinil. Prior to its agreement with Teva, however, Cephalon had been able to obtain sufficient amounts of modafinil to meet market demand for almost seven years without a supply agreement, and did not suddenly need such an agreement in December 2005. Again, Teva's agreement to supply Cephalon with modafinil was simply a subterfuge to conceal the fact that Cephalon was paying Teva not to compete with Cephalon's Provigil product for up to 6½ years.

107. Third, since Cephalon's patent claims were very weak, Teva's agreement to stay off the market until 2011 (or 2012) does not reflect a reasonable compromise of the patent suit based on the respective strength of Cephalon's claims and Teva's defenses. At the time of the settlement, there were approximately nine years remaining on Cephalon's patent, which is set to expire on October 6, 2014. Even though Teva was highly likely to win the patent case, it agreed to stay off the market for six of those nine remaining years. Thus, logic and economic rationality dictate that: (a) Teva must have received compensation for its agreement to stay off the market until 2011 or 2012; and (b) the above-described payments to Teva were, in fact, for its agreement to keep its generic version of Provigil off the market, rather than for the licenses and supply agreements that Defendants claim were the compensation for these payments.

108. Fourth, as of the date of its settlement with Cephalon, Teva was well aware that its ability to market a generic version of Provigil in 2011 or 2012 likely would be worth little (or nothing) because: (1) it knew of Cephalon's well-publicized efforts to convert all or most of the market demand for modafinil from Provigil to Nuvigil prior to the entry of generic versions of Provigil; and (2) Teva's generic product would not be AB-rated to--and thus would not be substitutable by pharmacists for--Nuvigil (since Nuvigil had a different dosage strength and/or formulation than Provigil). Thus, Teva knew that by the time it was permitted under its settlement agreement to sell its generic version of Provigil, its generic product was likely to generate little (if any) sales and profits, since it was likely that by that time, most (or all) of the demand for modafinil would have been converted to Nuvigil.

109. The agreement was intentionally structured in a manner that would buy Cephalon the time necessary to: (a) obtain FDA approval of its Nuvigil product; and (b) convert the market demand for modafinil from Provigil to Nuvigil. Indeed, prior to the agreement with Teva (and the



agreements with the other Generic Defendants), Cephalon had publicly stated its plan to launch Nuvigil in early 2006, while continuing to market Provigil. After the agreements, however, Cephalon publicly stated that its intent was: (a) to delay marketing Nuvigil until 2010--a year before the Generic Defendants were permitted to sell generic versions of Provigil under the agreements; and (b) to stop promoting/selling Provigil at that point, and to convert market demand for modafinil from Provigil to Nuvigil prior to the market entry of generic Provigil.

110. The purpose and effect of the agreement with Teva was made even clearer by Cephalon's Chief Executive Officer, Frank Baldino, Jr., who candidly explained the rise in Cephalon's stock price following the announcements of the settlements as follows:

“A lot of [Wall Street's enthusiasm for Cephalon's stock] is a result of the patent litigation getting resolved for Provigil. **We were able to get six more years of patent protection. That's \$4 billion in sales that no one expected.**”

*Philadelphia Business Journal*, March 20, 2006.

111. The announcement of Cephalon's first settlement (with Teva) created expectations that Cephalon would settle with the other Generic Defendants. These expectations were reasonable because, as explained above, it made little economic sense for Cephalon to settle with less than all of the Generic Defendants, since any one of them would have toppled Cephalon's modafinil monopoly if they had come to market with an AB-rated generic equivalent to modafinil.

## ii. The Ranbaxy Settlement

112. As anticipated, Cephalon continued its settlement efforts and reached an agreement with Ranbaxy on December 22, 2005. Under this settlement, Cephalon required that Ranbaxy refrain from marketing any generic version of Provigil until 2011 or 2012, unless another generic company launched a generic version of Provigil earlier than that date.

113. However, Ranbaxy would not agree to refrain from marketing generic Provigil until 2011 or 2012, without receiving significant compensation. Ranbaxy's chief negotiator sought to obtain "\$20-30 million" in value from the settlement. He would not have recommended the settlement to Ranbaxy management absent this compensation "because the economics of the settlement would be quite different."

114. Cephalon agreed to provide this compensation, in part, in the form of a supply agreement. Cephalon agreed to purchase modafinil API from Ranbaxy, despite the fact that Ranbaxy does not manufacture modafinil API itself, but rather sources the API from a third party manufacturer in India. Ranbaxy will pass API on to Cephalon at a substantial markup, and Cephalon will pay prices substantially higher than the price Cephalon paid to its existing supplier.

115. Cephalon also agreed to pay Ranbaxy up to \$5 million in exchange for a license to patent applications Ranbaxy held related to modafinil, despite the fact that Cephalon did not need the license to manufacture or sell Provigil or planned successor products, including Nuvigil.

116. The compensation Cephalon agreed to provide Ranbaxy was designed to, and did, induce Ranbaxy to settle the Provigil patent litigation and agree to refrain from marketing generic Provigil until 2011 or 2012.

**iii. The Mylan Settlement**

117. On January 9, 2006, Cephalon and Mylan entered a written agreement to settle their patent litigation. Under this settlement, Cephalon required that Mylan refrain from marketing any generic version of Provigil until 2011 or 2012, unless another generic company launched a generic version of Provigil earlier than that date.

118. In December 2005, just prior to settling, Mylan prepared a written projection with a 100% "probability factor" of launching a generic version of Provigil in June 2006. Mylan was

therefore unwilling to refrain from competing until 2011 or 2012 absent significant compensation. At Mylan's urging, Cephalon agreed to enter into simultaneous product development deals that provide significant guaranteed compensation for Mylan. Under these deals, Cephalon has paid Mylan, to date, at least \$45 million. Prior to its agreement with Mylan, Cephalon had expressed no interest to Mylan in the technology Mylan contributed to the product development deals.

119. The compensation Cephalon agreed to provide Mylan was designed to, and did, induce Mylan to settle the Provigil patent litigation and agree to refrain from marketing generic Provigil until 2011 or 2012.

**iv. The Barr Settlement**

120. On February 1, 2006, Cephalon entered written agreements with Barr and Barr's partner, Chemagis; Ltd. (together with its affiliates, "Chemagis") to settle Cephalon's patent litigation with Barr. Under the settlement, Cephalon required that Barr refrain from marketing any generic version of Provigil until 2011 or 2012, unless another generic company launched a generic version of Provigil earlier than that date.

121. Barr was unwilling, however, to settle the Provigil patent litigation based solely on terms that required Barr to refrain from marketing generic Provigil until 2011 or 2012. Instead, Barr insisted on additional compensation. Cephalon agreed to provide this compensation. It did so by (1) paying \$1 million for a license to a patent application Barr held related to modafinil that Cephalon did not need to manufacture or sell Provigil or planned successor products, including Nuvigil; (2) agreeing to purchase modafinil API directly from Chemagis (and indirectly from Barr via Barr's profit-sharing arrangement with Chemagis) at prices substantially higher than the price Cephalon paid to its existing supplier; and (3) settling unrelated patent litigation on terms favorable to Barr.

122. Since Barr had developed its generic version of Provigil in collaboration with Chemagis, which supplied modafinil API to Barr, any patent litigation settlement with Cephalon effectively required the assent of both Barr and Chemagis. Therefore, to secure Barr's agreement to refrain from marketing generic Provigil until 2011 or 2012, Cephalon was also willing to provide significant compensation to Chemagis.

123. At the same time it entered the patent settlement with Barr, Cephalon agreed to pay Chemagis \$4 million in exchange for a license to a patent and patent application Chemagis held related to modafinil that Cephalon did not need to manufacture or sell Provigil or planned successor products, including Nuvigil. Cephalon also entered into a product development deal with Chemagis. Under that deal, the parties agreed to collaborate on two projects. The first was the use of Chemagis drug delivery technology with an existing Cephalon drug product, for which Cephalon agreed to make \$20 million in guaranteed payments to Chemagis. The second was a project to be named later. Cephalon agreed to pay Chemagis at least \$20 million for the project to be named later.

124. The compensation Cephalon agreed to provide Barr and Chemagis was designed to, and did, induce Barr and Chemagis to settle the Provigil patent litigation and agree to refrain from marketing generic Provigil until 2011 or 2012.

**G. DEFENDANTS' CONDUCT ALSO DELAYS ENTRY BY APOTEX**

125. On March 30, 2005, Apotex, Inc. filed its ANDA number 77-667 for a generic version of Provigil. Apotex produces more than 260 generic pharmaceuticals in over 4000 dosages and formats to over 115 countries around the world, according to Apotex. Apotex has sufficient knowledge, expertise, capital, facilities, marketing prowess, and access to any raw materials necessary to manufacture and sell generic Provigil in the United States.



126. Apotex's ANDA filing included a Paragraph III certification stating that it would not sell until the expiration of the patents then listed for Provigil in the FDA's Orange Book. Although Apotex did not originally file a Paragraph IV certification that the RE '516 patent was invalid or not infringed, it believed it had no reason to do so, because four other generic companies were already engaged in litigation over that patent.

127. When Apotex learned through the various press releases that the Generic Defendants had settled their lawsuits with Cephalon with an agreement not to pursue their claims concerning the RE '516 Patent, Apotex changed its certification from a Paragraph III certification to a Paragraph IV certification, to specifically state the RE '516 Patent was either invalid or not infringed.

128. Apotex received tentative approval for its ANDA on December 29, 2006, and the only known impediment to Apotex's receipt of final FDA approval (and the entry of Apotex's generic Provigil) is that the Generic Defendants have not triggered their 180 day exclusivity period. That period would have been triggered had the Generic Defendants either launched their products in 2006, as they had planned to do, or had continued to prosecute their patent cases to judgment. Instead, as a result of the Exclusion Payment Agreements, all four Generic Defendants have agreed not to enter before April 2012, leaving their 180 day exclusivity period in place and blocking final approval and entry of subsequent generics like Apotex.

129. Although Cephalon has received a Paragraph IV certification from Apotex, Cephalon has not brought suit under Hatch-Waxman as it is entitled to do, either as a result of an express or tacit agreement with the Generic Defendants, or of its own accord. Cephalon declined to bring to bring suit because it knew that doing so would put the RE '516 patent at risk of a finding of invalidity or non-infringement. However, by refraining from filing suit, Cephalon could



avoid any determination of the invalidity or non-infringement of its patent because Apotex, as a second generic, would lack standing to bring a declaratory judgment action. Nevertheless, on June 26, 2006, Apotex filed an action seeking a declaratory judgment that the RE '516 Patent is either invalid or not infringed by Apotex's generic Provigil. (*Apotex, Inc. v. Cephalon, Inc., et al.*, Civ. A. No. Case 2:06-cv-02768 (E.D. Pa.)). Cephalon challenged Apotex's right to bring a declaratory judgment action arguing there was no case or controversy because Apotex did not face a "reasonable apprehension of imminent suit," which it argued, based on then-existing law, was a prerequisite for standing under what it termed "clear and controlling" precedent. Cephalon, Inc.'s Motion to Dismiss and to Strike, Civ. A. No. Case 2:06-cv-02768, D.E. # 31, at 54-55 (E.D. Pa.). Thus, Cephalon likely believed that by paying off the first filers to drop their patent case and delaying their entry into the market, and then refraining from filing suit against Apotex (the only secondary entrant), it could forestall the only remaining manufacturer of generic Provigil from entering as well.

130. Thus, Defendants' conduct has delayed not only less expensive generic Provigil from the Generic Defendants; Defendants' conduct has also created a bottleneck which has delayed the introduction of generic Provigil by Apotex.

131. Moreover, the agreements between Cephalon and the Generic Defendants which leave the Generic Defendants' 180-day exclusivity period in place is not necessary for the settlement of the patent litigation and constitutes an ancillary restraint of trade.

#### **H. THE BROAD EFFECTS OF CEPHALON'S ANTICOMPETITIVE AGREEMENTS**

132. The settlement agreements prevent each of Teva, Ranbaxy, Mylan, and Barr from selling generic Provigil at issue in the patent litigation, as well as developing and marketing any other

generic versions of Provigil. In addition, Teva and Mylan also agreed not to develop, market, or sell generic equivalents of successor products.

133. Furthermore, under their agreements with Cephalon, the Generic Defendants may not sell generic products whether or not they infringe Cephalon's Particle Size Patent. Cephalon's patent lawsuit, in contrast, had the potential to restrict only sales of these companies' current versions of generic Provigil, the products at issue in the litigation.

134. Absent the Generic Defendants' illegal agreements not to compete with Cephalon for up to 6½ years, each and all of the Generic Defendants would have obtained final FDA approval to sell their generic versions of Provigil, and would have commenced selling their less expensive generic versions of Provigil by no later than January 2006.

135. Absent the illegal "exclusion payments" they received from Cephalon, the Generic Defendants would have been motivated to begin selling their generic version of Provigil as soon as possible, in order to reap a substantial return on the significant investment each had made in developing and seeking FDA approval for their generic versions of Provigil. Additionally, each of the Generic Defendants would have been motivated to come to market promptly because each knew that if it did not come to market, one of the other Generic Defendants would likely do so, and capture the significant sales of generic Provigil.

136. The exclusion payments made by Cephalon to the Generic Defendants deny consumers "access to potentially major savings – here perhaps half of the \$4 billion Cephalon's CEO [Frank Baldino, Jr.] claimed 'no one' expected his company to earn. By settling with all generic applicants, a brand firm [Cephalon] ensures that consumers never have a chance to see those savings." *Remarks by Jon Leibowitz, Commissioner, Federal Trade Commission, Second Annual In-House Counsel's Forum on Pharmaceutical Antitrust, April 24, 2006.*

137. On or about March 28, 2006, Cephalon received a six-month pediatric exclusivity extension from the FDA, which applied only to exclusivities that were not expired on the date the extension was granted. Cephalon's Orphan Drug exclusivity for Provigil expired on December 24, 2005, over 90 days before Cephalon's receipt of a pediatric extension on March 28, 2006. As a result, the Generic Defendants would not have been prevented from obtaining final FDA approval to sell their generic versions of Provigil prior to Cephalon's receipt of the pediatric extension.

138. With Provigil's future secured, Cephalon reversed course on its plans for its flagship product. Prior to securing the Generic Defendants' agreements not to compete until 2011 or 2012, Cephalon had cut back on promotion of Provigil in anticipation of generic entry in mid-2006. After eliminating the threat of generic entry, however, Cephalon advised the investment community that it "reinvigorat[ed]" its Provigil marketing programs. In addition, Cephalon suspended its plans to launch an authorized generic version of Provigil and postponed its anticipated launch of Nuvigil.

#### **I. EFFECT ON INTERSTATE COMMERCE**

139. At all material times, Provigil, manufactured and sold by Defendant Cephalon, was shipped across state lines and sold to customers located outside its state of manufacture.

140. During the relevant time period, in connection with the purchase and sale of Provigil, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

141. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Defendants, as charged in this Complaint, were within the flow of, and have substantially affected, interstate commerce.

**J. MONOPOLY POWER**

142. Through the anticompetitive conduct alleged herein, Cephalon was able to profitably charge supracompetitive prices for modafinil without losing substantial sales, and thus, by definition, maintained monopoly power with respect to modafinil sold in the United States. To the extent that Plaintiff is legally required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiff alleges that the relevant product market is modafinil products--*i.e.*, Provigil (in all its forms and dosage strengths), and AB-rated bioequivalent version of Provigil. There are no reasonably interchangeable drug products that are available to prescribing physicians for the indications for which modafinil is prescribed. For the entire period relevant to this case, Cephalon has been able to profitably maintain the price of its branded modafinil product well above competitive levels without losing substantial sales.

143. The relevant geographic market is the United States and its territories.

144. Cephalon's market share in the relevant market is and was 100% at all times relevant to this complaint.

145. Defendants' actions are part of, and in furtherance of, the illegal restraint of trade and monopolization alleged herein, were authorized, ordered or done by Defendants' officers, agents, employees or representatives while actively engaged in the management of Defendants' affairs.

146. Defendants' illegal acts to prevent the introduction and/or dissemination into the U.S. marketplace of any generic version of Provigil resulted in Plaintiffs and the Class paying more than they would have paid for modafinil, absent Defendants' illegal conduct.



**K. EFFECT ON COMPETITION AND DAMAGES TO PLAINTIFFS AND CLASS**

147. Defendants' exclusionary conduct has delayed or prevented the sale of generic modafinil in the United States, and unlawfully enabled Defendants to sell Provigil at artificially inflated prices. But for Defendants' illegal conduct, generic competitors would have been able to successfully market generic versions of Provigil capsules by June 2006, and additional generic competitors would have entered the market thereafter.

148. If manufacturers of generic modafinil had entered the marketplace and effectively competed with Defendants earlier, as set forth above, Plaintiffs and other members of the Class would have substituted lower-priced generic modafinil for the higher-priced brand name Provigil for some or all of their modafinil requirements, and/or would have received a lower price (and/or discounts) on some or all of their remaining Provigil purchases.

149. Cephalon has effectively paid the Generic Defendants potentially more than they otherwise would have earned by competing and provided a date certain for the sale of their generic versions of Provigil. However, the result of such exclusionary agreements ensure that "these rivals will have *carte blanche* to avoid competition and share resulting profits, and we will see minimal competition before patent expiration. Such results fly in the face of Congress' efforts in 1984 to create incentives for early generic entry, and in 2003 to ensure review of these settlements that troubled them." *Remarks by Jon Leibowitz, Commissioner, Federal Trade Commission, Second Annual In-House Counsel's Forum on Pharmaceutical Antitrust, April 24, 2006*

150. During the relevant period, Plaintiffs and other members of the Class purchased substantial amounts of Provigil from Defendants. As a result of Defendants' illegal conduct alleged herein, Plaintiffs and other members of the Class were compelled to pay, and did pay, artificially inflated prices for their modafinil requirements. Plaintiffs and the other Class members



paid prices for modafinil that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Class members were deprived of the opportunity to purchase lower-priced generic modafinil instead of expensive brand name Provigil; (2) Class members paid artificially inflated prices for generic modafinil and/or (3) the price of branded Provigil was artificially inflated by Defendants' illegal conduct. As a consequence, Plaintiffs and other members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges.

### **COUNT I**

#### **(For Injunctive Relief Under Section 16 of the Clayton Act for Defendants' Violation of Section 1 of the Sherman Act)**

151. Plaintiffs repeat and incorporate the preceding paragraphs as though set forth herein.

152. Beginning on or about December 9, 2005, Cephalon and each of the Generic Defendants engaged in continuing illegal contracts, combinations and conspiracies in restraint of trade, the purpose and effect of which was to: (a) allocate all sales of modafinil in the United States to Cephalon; (b) prevent the sale of generic version of modafinil in the United States, thereby protecting Provigil from any generic competition for up to 6½ years; and (c) fix the price at which purchasers would pay for Provigil at the higher, branded price.

153. By entering into these unlawful conspiracies, Defendants have unlawfully conspired in restraint of trade and committed a violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. Defendants' agreements are horizontal market allocation and price-fixing agreements between actual or potential competitors, and thus are *per se* violations of Section 1. In the alternative, Defendants' agreements are unreasonable restraints of trade in violation of Section 1, when viewed under a "quick look" or "rule of reason" mode of analysis.

154. Plaintiffs and the members of the Class have been injured in their business and property by reason of Defendants' unlawful contract, combination and conspiracy. Plaintiffs and the Class members have paid more for their purchases of Provigil than they would have paid absent Defendants' illegal conduct, and/or were prevented from substituting a cheaper generic for their purchases of the more expensive Provigil.

155. As a result of Cephalon's illegal conduct, Plaintiffs and the Class paid more than they would have paid for modafinil, absent Cephalon's illegal conduct. But for Cephalon's illegal conduct, competitors would have begun marketing generic versions of Provigil well before they actually did, and/or would have been able to market such versions more successfully.

156. If manufacturers of generic modafinil entered the market and competed with Cephalon in a full and timely fashion, Plaintiffs and other Class members would have substituted lower-priced generic modafinil for the higher-priced brand name Provigil for some or all of their modafinil requirements, and/or would have received lower prices on some or all of their remaining Provigil purchases.

157. During the relevant period, Plaintiffs and the other Class members purchased substantial amounts of Provigil. As a result of Cephalon's illegal conduct alleged herein, Plaintiffs and the other Class members were compelled to pay, and did pay, artificially inflated prices for their modafinil requirements. Plaintiffs and all of the other Class members paid prices for modafinil that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) class members were deprived of the opportunity to purchase lower-priced generic modafinil instead of expensive brand name Provigil; (2) class members were forced to pay artificially inflated prices for generic modafinil and/or (3) the price of branded Provigil was artificially inflated by Defendants' illegal conduct.

158. Plaintiffs and the Class, pursuant to Rule 57 of the Federal Rules of Civil Procedure and 18 U.S.C. § 2201(a), hereby seek a declaratory judgment that Defendants' conduct violates Section 1 of the Sherman Act.

159. Plaintiffs and the Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to remedy the anti-competitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar anti-competitive conduct does not occur in the future.

## **COUNT II**

### **(For Injunctive Relief under Section 16 of the Clayton Act for Defendant's Violation of Section 2 of the Sherman Act Against Cephalon Only)**

160. Plaintiffs repeat and incorporate the preceding paragraphs as though set forth herein.

161. Cephalon used various willful and exclusionary means as part of a scheme described herein to improperly maintain and extend their monopoly power in the modafinil market, as detailed above.

162. The goal, purpose and/or effect of Cephalon's scheme was to prevent, delay, and/or minimize the success of the entry of generic modafinil competitors which would have sold generic modafinil in the United States at prices significantly below Defendants' prices for Provigil, which would have effectively caused the average market price of modafinil to decline dramatically.

163. The goal, purpose and/or effect of Cephalon's scheme was also to maintain and extend Cephalon's monopoly power with respect to modafinil. Cephalon's illegal scheme to prevent, delay, and/or minimize the success of the introduction into the United States marketplace of any generic version of Provigil enabled Cephalon to continue charging supra-competitive prices for modafinil without a substantial loss of sales.

164. As a result of Cephalon's illegal conduct, Plaintiffs and the Class paid more than they would have paid for modafinil, absent Cephalon's illegal conduct. But for Cephalon's illegal conduct, competitors would have begun marketing generic versions of Provigil well before they actually did, and/or would have been able to market such versions more successfully.

165. If manufacturers of generic modafinil entered the market and competed with Cephalon in a full and timely fashion, Plaintiffs and other Class members would have substituted lower-priced generic modafinil for the higher-priced brand name Provigil for some or all of their modafinil requirements, and/or would have received lower prices on some or all of their remaining Provigil purchases.

166. During the relevant period, Plaintiffs and the other Class members purchased substantial amounts of Provigil. As a result of Cephalon's illegal conduct alleged herein, Plaintiffs and the other Class members were compelled to pay, and did pay, artificially inflated prices for their modafinil requirements. Plaintiffs and all of the other Class members paid prices for modafinil that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) class members were deprived of the opportunity to purchase lower-priced generic modafinil instead of expensive brand name Provigil; (2) class members were forced to pay artificially inflated prices for generic modafinil and/or (3) the price of branded Provigil was artificially inflated by Defendants' illegal conduct.

167. Cephalon's scheme was in the aggregate an act of monopolization undertaken with the specific intent to monopolize the market for modafinil in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

168. Plaintiffs and the Class, pursuant to Rule 57 of the Federal Rules of Civil Procedure and 18 U.S.C. § 2201(a), hereby seek a declaratory judgment that Cephalon's conduct violates Section 2 of the Sherman Act.

169. Plaintiffs and the Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to remedy the anti-competitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar anti-competitive conduct does not occur in the future.

### **COUNT III**

#### **(Conspiracy to Monopolize In Violation of Section 2 of the Sherman Act Against All Defendants)**

170. Plaintiffs repeat and incorporate the preceding paragraphs as though set forth herein.

171. As detailed above, the Generic Defendants conspired with Cephalon to monopolize the modafinil market by, inter alia, agreeing to keep their generic versions of modafinil off the market for up to 6½ years, in exchange for substantial cash payments.

172. During the relevant period, Plaintiffs and the other Class members purchased substantial amounts of Provigil directly from Cephalon. As a result of Cephalon's illegal conduct alleged herein, Plaintiffs and the other Class members were compelled to pay, and did pay, artificially inflated prices for their modafinil requirements. Plaintiffs and all of the other Class members paid prices for modafinil that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) class members were deprived of the opportunity to purchase lower-priced generic modafinil instead of expensive brand name



Provigil; (2) class members were forced to pay artificially inflated prices for generic modafinil and/or (3) the price of branded Provigil was artificially inflated by Defendants' illegal conduct/

#### **COUNT IV**

##### **(For Compensatory and Multiple Damages under the Antitrust and/or Consumer Protection Statutes of the Indirect Purchaser States)**

173. Plaintiffs repeat and reallege the preceding and subsequent paragraphs as though set forth herein.

174. Defendants' conduct described herein constitutes unlawful acts of monopolization and attempts to monopolize, as well as prohibited practices and unconscionable conduct under the antitrust and/or unfair and deceptive trade practices acts of the Indirect Purchaser States, as follows:

- (a) Arizona: The aforementioned practices by Defendants were and are in violation of the Arizona Uniform State Antitrust Act, Ariz. Rev. Stat. §§ 44-1401, *et seq.*, the Arizona Consumer Fraud Act, Ariz. Rev. Stat. §§ 44-1521, *et seq.*, and the Constitution of the State of Arizona, Article 14, §15;
- (b) California: The aforementioned practices by Defendants were and are in violation of the Cartwright Act, Cal. Bus. & Prof. Code §§ 16700, *et seq.*, and the California Unfair Competition Act, Cal. Bus. & Prof. Code §§ 17200, *et seq.*;
- (c) District of Columbia: The aforementioned practices by Defendants were and are in violation of the District of Columbia Antitrust Act, D.C. Code §§ 28-4501, *et seq.*;
- (d) Florida: The aforementioned practices by Defendants were and are in violation of the Florida Antitrust Act, Fla. Stat. Ann. §§ 542.15, *et seq.*, and the Florida Deceptive and Unfair Trade Practices Act (DUTPA), Fla. Stat. Ann. §§ 501.201, *et seq.*;
- (e) Hawaii: The aforementioned practices by Defendants were and are in violation of Hawaii Revised Statutes §§ 480-2, 480-3, and 480-4.
- (f) Iowa: The aforementioned practices by Defendants were and are in violation of the Iowa Competition Law, Iowa Code §§ 553.4, 553.5 (1997);
- (g) Kansas: The aforementioned practices by Defendants were and are in violation of the Kansas Monopolies and Unfair Trade Act, Kan. Stat. Ann. §§ 50-101, *et seq.*, and the Kansas Consumer Protection Act, Kan. Stat. Ann. §§ 50-623, *et seq.*;

- (h) Kentucky: The aforementioned practices by Defendants were and are in violation of the Kentucky Consumer Protection Act, Ky. Rev. Stat. Ann. §§ 367.110, *et seq.*, and the Kentucky Unfair Trade Practices Act, Ky. Rev. Stat. Ann §§ 365.020, *et seq.*;
- (i) Louisiana: The aforementioned practices by Defendants were and are in violation of the Louisiana Monopolies Law, La. Rev. Stat. Ann. §§ 51:121, *et seq.*, and the Louisiana Unfair Trade Practices and Consumer Protection Law, La. Rev. Stat. Ann. §§ 51:1401, *et seq.*;
- (j) Maine: The aforementioned practices by Defendants were and are in violation of the Maine Monopolies and Profiteering Statute, Me. Rev. Stat. Ann. tit. 10, §§ 1101, *et seq.*, and the Maine Unfair Trade Practices Act, Me. Rev. Stat. Ann. tit. 5, §§ 205-A, *et seq.*;
- (k) Massachusetts: The aforementioned practices by Defendants were and are in violation of the Massachusetts Antitrust Act, Mass. Gen. Laws, ch. 93, and the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93A;
- (l) Michigan: The aforementioned practices by Defendants were and are in violation of the Michigan Antitrust Reform Act, Mich. Comp. Laws §§445.771, *et seq.*, and the Michigan Consumer Protection Act, §§ 445.901, *et seq.*;
- (m) Minnesota: The aforementioned practices by Defendants were and are in violation of the Minnesota Antitrust Law of 1971, Minn. Stat. §§ 325D.49, *et seq.*, and the Minnesota Consumer Fraud Act, Minn. Stat §§ 325F.67, *et seq.*;
- (n) Mississippi: The aforementioned practices by Defendant were and are in violation of the Mississippi antitrust statute, Miss. Code Ann. §§75-21-1 *et seq.*;
- (o) Nebraska: The aforementioned practices by Defendant were and are in violation of the Nebraska Consumer Protection Act, Neb. Rev. Stat. § 59-1601, *et seq.*;
- (p) Nevada: The aforementioned practices by Defendants were and are in violation of the Nevada Unfair Trade Practices Act, Nev. Rev. Stat. §§ 598A.010, *et seq.*, and the Nevada Deceptive Trade Practices Act, Nev. Rev. Stat. §§ 598.0903, *et seq.*;
- (q) New Mexico: The aforementioned practices by Defendants were and are in violation of the New Mexico Antitrust Act, N.M. Stat. Ann. §§ 57-1-1, *et seq.*, and the New Mexico Unfair Practices Act, N.M. Stat. Ann. §§ 57-12-1, *et seq.*;
- (r) New York: The aforementioned practices by Defendants were and are in violation of the Donnelly Act, N.Y. Gen. Bus. Law §§ 340, *et seq.*, and the New York Deceptive Acts and Practices Act, N.Y. Gen. Bus. Law §§ 349, *et seq.*;
- (s) North Carolina: The aforementioned practices by Defendants were and are in violation of North Carolina's antitrust and unfair competition law, N.C. Gen. Stat. §§ 75-1, *et seq.*;

- (t) North Dakota: The aforementioned practices by Defendants were and are in violation of the North Dakota Antitrust Act, N.D. Cent. Code §§ 51-08.1-01, *et seq.*, and the North Dakota Consumer Fraud Act, N.D. Cent. Code §§ 51-15-01, *et seq.*;
- (u) South Dakota: The aforementioned practices of Defendants were and are in violation of South Dakota's antitrust law, S.D. Codified Laws §§ 37-1-3, *et seq.*, and deceptive trade practices and consumer protection law, S.D. Codified Laws §§ 37-24-1, *et seq.*;
- (v) Tennessee: The aforementioned practices of Defendants were and are in violation of the Tennessee Trade Practices Act, Tenn. Code Ann. §§ 47-25-101, *et seq.*, and the Consumer Protection Act, Tenn. Code Ann. §§ 47-18-101, *et seq.*;
- (w) Utah: The aforementioned practices of Defendants were and are in violation of the Utah Trade Practices Act, Utah Code Ann. §§ 13-5-1, *et seq.*, the Utah Consumer Sales Practices Act, Utah Code Ann. §§ 13-11-1, *et seq.*, and Utah Code Ann. § 76-10-919;
- (x) Vermont: The aforementioned practices of Defendants were and are in violation of the Vermont Consumer Fraud Act, Vt. Stat. Ann. tit. 9, §§ 2451, *et seq.*;
- (y) West Virginia: The aforementioned practices by Defendants were and are in violation of the West Virginia Antitrust Act, W.Va. Code §§ 47-18-1, *et seq.*, and the West Virginia Consumer Credit and Protection Act, W. Va. Code §§ 46A-6-101, *et seq.*; and
- (z) Wisconsin: The aforementioned practices by Defendants were and are in violation of the Wisconsin Antitrust Act, Wis. Stat. §§ 133.01, *et seq.*, and the Wisconsin Unfair Trade Practices Act, Wis. Stat. §§ 100.20, *et seq.*

175. As a result of the conduct described above, Plaintiffs and the Class have sustained and will continue to sustain substantial losses and damage to their businesses and property in the form of, *inter alia*, being deprived of the ability to purchase less expensive, generic versions of Provigil, and paying prices for such products that were higher than they would have been but for Defendants' improper actions. The injury to Plaintiffs and the Class is the type of injury antitrust laws and the consumer protection statutes were designed to prevent, and the injury flows from Defendants' unlawful conduct. The full amount of such damages are presently unknown and will be determined after discovery and upon proof at trial.

176. Plaintiffs and the Class seek damages, multiple damages, treble damages, and other damages as permitted by state law, for their injuries caused by these violations pursuant to these statutes.

177. Plaintiff and the Class further seek a declaratory judgment that Defendants' conduct in seeking to prevent competition through the scheme set forth herein is unlawful, and equitable and injunctive relief pursuant to the laws of the Indirect Purchaser States to correct for the anti-competitive market effects and other harms to purchasers caused by the unlawful conduct of Defendants, and other relief so as to assure that similar conduct does not occur in the future.

178. The conduct complained of herein has "substantially affected" the people of Wisconsin and had impacts in Wisconsin, and the actions and transactions alleged herein have occurred "primarily and substantially" within Massachusetts, as those terms are understood under Wisconsin and Massachusetts law. To the extent that any notice needs to be sent pursuant to any of the statutes referenced in this Count, such notice will be sent as required by the Court.

179. Defendants intended by their conduct to have pharmacies in each of the individual states charge higher prices for Provigil as a result of the lack of competition from AB-rated generic versions of Provigil, including for transactions that occurred purely intrastate. Sales of Provigil at supracompetitive prices did occur in each state, and the effects of the anticompetitive conduct were felt in each state.

180. To the extent that New York law so requires, Plaintiffs hereby forgo any minimum or punitive damages in order to preserve the right of class members to recover by way of a class action.



**COUNT V**

**(For Restitution, Disgorgement and Constructive  
Trust for Unjust Enrichment by Defendants)**

181. Plaintiffs repeat and reallege the preceding paragraphs as though set forth herein.

182. As a result of their unlawful conduct described above, Defendants have been and will continue to be unjustly enriched. Cephalon has been unjustly enriched, to the detriment of Plaintiffs and the Class, by the receipt of unlawfully inflated prices and illegal profits on their sale of Provigil. Separately, the Generic Defendants have been unjustly enriched, to the detriment of Plaintiffs and the Class, by the receipt of any and all payments made to them by Cephalon to keep generic Provigil off the market. Defendants have benefited from their unlawful acts and it would be inequitable for Defendants to be permitted to retain any of their ill-gotten gains, including, but not limited to, all of the payments made to the Generic Defendants by Cephalon and the gains resulting from the overpayments for Provigil made by Plaintiffs and the Class.

183. Plaintiffs and members of the Class are entitled to some or all of the total amount of Defendants' ill-gotten gains resulting from Defendants' unlawful, unjust and inequitable conduct. Plaintiffs and the Class are entitled to restitution and/or the establishment of a constructive trust consisting of all ill-gotten gains from which Plaintiffs and the Class members may make claims on a *pro rata* basis.

184. As a result, Plaintiffs and the Class intend to seek damages for unjust enrichment under the laws of the states identified in Count IV, paragraph 175.



**PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiffs pray that the Court:

- a. Determine that this action may be maintained as a class action pursuant to Rules 23(a), 23(b)(2) and 23(b)(3) of the Federal Rules of Civil Procedure; and declare Plaintiffs as Class representatives;
- b. Declare the conduct alleged herein to be in violation of Sections 1 and 2 of the Sherman Act, of the statutes of the Indirect Purchaser States set forth above, and the common law of unjust enrichment;
- c. Award Plaintiffs and each member of the Class damages and, where applicable, treble, multiple, and other damages, including interest;
- d. Award Plaintiffs and each member of the Class the amounts by which Defendants have been unjustly enriched;
- e. Enjoin Defendants from continuing the illegal activities alleged herein;
- f. Award Plaintiffs and the Class their costs of suit, including reasonable attorneys' fees and expenses as provided by law; and
- g. Award the Class further relief as the Court deems just and necessary.

**JURY TRIAL DEMAND**

Pursuant to Fed. R. Civ. P. 38(b), Plaintiffs demand a trial by jury of all of the claims asserted in this Complaint so triable.

Dated: August 10, 2009

JHM6596

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**CERTIFICATE OF SERVICE**

I, Joseph H. Meltzer, hereby certify that on August 10, 2009, the Consolidated Amended Class Action Complaint was filed with the Clerk of Court, and made available for viewing and downloading from the court's ECF system by all counsel.

JHM6596

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Joseph H. Meltzer

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